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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,094	01/24/2005	Enrico Gerardus Albertus Linders	70059USPCT	9236
22847 7590 09/18/2007 SYNGENTA BIOTECHNOLOGY, INC. PATENT DEPARTMENT 3054 CORNWALLIS ROAD P.O. BOX 12257 RESEARCH TRIANGLE PARK, NC 27709-2257			EXAMINER ROBINSON, KEITH O NEAL	
			ART UNIT 1638	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,094

Applicant(s)

LINDERS ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 17-24, 27-33, 35, 41-43 and 46-52 is/are pending in the application.
- 4a) Of the above claim(s) 27-33, 35, 41-43 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17-24, 46-49, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:2/13/06;3/31/06;7/12/06;2/16/07;3/29/07.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I (claims 1-11, 17-24 and 46-52) in the reply filed on June 11, 2007 is acknowledged. In addition, Applicant has elected primer O20 (SEQ ID NO: 1). It is noted that claim 50 is drawn to the non-elected primer Y13 (SEQ ID NO: 2) and will not be examined.

2. Claims 27-33, 35, 41-43 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 11, 2007.

3. Claims 1-11, 17-24 and 46-49, 51 and 52 are under examination.

Claim Objections

4. Claims 22-24, 46, 47, 51 and 52 are objected to because of the following informalities:

Claim 22 should read: - - A [Seed] seed of [a] the plant according to claim 1. - -

Claim 23 should read: - - A [Fruit] fruit or a part of [a] the plant according to claim 1. - -

Claim 24 should read: - - A [Part] part of [a] the plant according to claim 1, wherein said part is pollen, ovule or embryo. - -

Claim 46 should read: - - A [Seed] seed of [a] the plant according to claim 11. - -

Claim 47 should read: - - A [Fruit] fruit or a part of [a] the plant according to claim 11. - -

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Claim 51 should read: - - A [Seed] seed of [a] the plant according to claim 48. - -

Claim 52 should read: - - A [Fruit] fruit or a part of [a] the plant according to claim 48. - -

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-11, 17-24 and 46-49, 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

See MPEP 2163(I) where it states “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116”.

The specification only provides evidence that Applicant was in possession of *B. oleracea* line CFL667, wherein said line was derived from an interspecific cross of clubroot resistant Chinese cabbage F1 hybrid from Japan commercially available under the name 'Parkin' and an disclosed broccoli plant (see, for example, pages 10-11) and not each and every *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant as is broadly claimed.

MPEP 2163(I) also states, "[a]n application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 et seq. See *Enzo Biochem*, 323 F.3d at 965, 63 USPQ2d at 1614 ("reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material").

MPEP 2163.02 states, "[u]nder *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed".

In the instant case, Applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of *B. oleracea* line CFL667 (see page 11 of the specification) and not each and every *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant as is broadly claimed.

Thus, based on the disclosure of the specification, Applicant has only shown possession of *B. oleracea* line CFL667.

See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

7. Claims 1-11, 17-24 and 46-49, 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to any *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

Since the plant is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily

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available to the public. Thus, a deposit is required for enablement purposes. A deposit of seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

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It is noted that on page 11 of the specification *B. oleracea* line CFL667 was deposited with NCIMB under accession NCIMB 41134; however, the specification fails to provide any deposit information detailing the conditions under which *B. oleracea* line CFL667 was deposited. The deposit of the seed should comply 37 CFR 1.801-1.809 as indicated above.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 11, 17, 19, 21-24, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang et al (HortScience 20(3): 457-458, 1985). The claims read on any *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

Chiang et al disclose male fertile and male sterile *B. oleracea* plants resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant (see page 457, 1st column, 1st paragraph, where it discloses single dominant gene inheritance; see 457, 1st column, 2nd paragraph and Figure 1, where it discloses six clubroot resistant breeding lines).

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to

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distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

10. Claims 1-4, 11, 17, 19, 22-24, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Baggett et al (HortScience 20(4): 784-785, 1985). The claims read on any *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

Baggett et al disclose a *B. oleracea* plant resistant to clubroot disease (see page 784, 1st column, 2nd paragraph and page 785, 1st column, 2nd full paragraph).

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

11. Claims 1-4, 11, 17, 19, 22-24, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang et al (Can. J. Plant Sci. 69: 337-340, 1989). The claims

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read on any *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

Chiang et al disclose a *B. oleracea* plant resistant to clubroot disease (see page 337, 1st column last two lines to page 339, 2nd column, lines 1-3).

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-11, 17-24 and 46-49, 51 and 52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Landry et al (Genome 35(3): 409-420, 1992). The claims read on any *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

With regards to claims 1-5, 7, 8, 11, 17, 19, 22-24, 46 and 47, Landry et al teach a *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant, wherein resistance is linked to a molecular marker (see page 410, 1st column, 4th paragraph, where it teaches clubroot resistant line 86-16-5 and page 417, 1st column, last paragraph to 2nd column, lines 3-4, where it teaches that two markers are associated with linkage group 1 (monogenic) and that alleles of line 86-16-5 are dominant for resistance to clubroot).

With regards to claim 6, 48, 49, 51 and 52, Landry et al do not teach resistance linked to a molecular marker obtainable by PCR amplification using primer O20; however, it would be obvious to one of ordinary skill in the art that different markers

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could be used in identifying clubroot resistance. In fact, the teachings of Landry et al would motivate one of ordinary skill in the art to find other markers associated with clubroot resistance in *B. oleracea* plants because Landry et al have taught linkage groups associated with clubroot resistance in *B. oleracea* plants (see page 417, Figure 6).

With regards to claims 9 and 10, Landry et al do not teach resistance obtainable from a clubroot resistant *B. rapa* plant nor the Chinese cabbage hybrid 'Parkin'; however, it would be obvious to one of ordinary skill in the art that clubroot resistance would come from other different sources of *Brassica* spp and that the choice of any particular *Brassica* spp depends on the breeder's goals. For example, Landry et al teach the use of 15 differential hosts for screening for clubroot resistant Brassicas (see page 410, 1st column, 1st full paragraph).

With regards to claims 18 and 20, Landry et al do not teach *B. oleracea* plants heterozygous for clubroot resistance nor hybrid *B. oleracea* plants; however, it would be obvious one of ordinary skill in the art that heterozygous and hybrid *B. oleracea* plants could be used because Landry et al teach that alleles for resistance to clubroot are dominant (see page 417, 2nd column, lines 3-4).

With regards to claim 21, Landry et al do not teach a cytoplasmic male sterile *B. oleracea* plant having clubroot resistance; however, Landry et al do teach a male sterile *B. oleracea* plant (see page 410, 1st column, last paragraph) and it would be obvious to one of ordinary skill in the art how to develop a cytoplasmic male sterile *B. oleracea* plant having clubroot resistance.

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Landry et al to produce a *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant.

One of ordinary skill in the art would have been motivated to use the teachings of Landry et al because Landry et al teach that the use of genetically resistant cultivars has been the only viable method of controlling clubroot disease (see page 410, 1st column, lines 1-3).

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Landry et al in producing a *B. oleracea* plant resistant to clubroot disease, wherein the resistance to clubroot is monogenic and dominant (see, for example, page 416, Figure 5).

Conclusion

16. No claims are allowed.

Contact Information

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is (571) 272-2918. The examiner can normally be reached Monday – Friday, 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.

/Medina A. Ibrahim/
Primary Examiner
AU 1638

September 14, 2007